PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Conf. No. 4572
	)	
Feng Xu	)	Group Art Unit 1632
	)	
Serial No: 10/567,940	)	Examiner: Michael C. Wilson
	)	
Filed: September 27, 2006	)	Atty. Docket No. PP019817.0003

For: **INACTIVATED HOST CELL DELIVERY OF POLYNUCLEOTIDES ENCODING IMMUNOGENS**

RESPONSE TO RESTRICTION REQUIREMENT

U.S. Patent and Trademark Office
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This paper responds to the Restriction Requirement mailed February 24, 2009. Charge extension fees to our Deposit Account No. 19-0733. Applicant provisionally elects Group I (claims 1-13, 23-29, and 34-40) and the species *Shigella* **with traverse**. Claims 1-13, 23-25, 27, 34-36, and 37 read on the provisionally elected species.

The Examiner contends that the special technical feature of "administering an inactivated non-mammalian cell to a mammal, wherein the non-mammalian cell comprises a nucleic acid sequence encoding an immunogen under the control of a promoter that functions in eukaryotic cells" is disclosed in Li (*J. Allergy Clin. Immunol. 112*, 159-67, July 2003). Because of this, rather than considering claims 1 and 8 as linking claims, the Examiner has divided claims 1 and

8 and their dependent claims into three groups. Li does not support restricting the claims in this way.

On page 3, the Examiner cites Li as teaching a pET24 vector containing the bacteriophage T7 promoter, cites Moss (U.S. Patent 5,126,251) as teaching expression in mammalian cells of a gene under the control of the T7 promoter, and asserts that Li therefore teaches a promoter that is "functional in eukaryotic cells." To the contrary, Moss actually explains why Li's T7 promoter would *not* function in eukaryotic cells.

Absent other modifications, eukaryotic cells cannot express genes under the control of the T7 promoter because eukaryotic cells lack the T7 RNA polymerase. The only reason that Moss' cells can express RNA from DNA having a T7 promoter is because the cells also contain the foreign T7 RNA polymerase. See col. 1, lines 55-57, where Moss teaches "construction of a stable mammalian cell line that expresses a foreign RNA polymerase gene." The foreign RNA polymerase is the T7 RNA polymerase. Col. 2, lines 62-65. The presence of the foreign T7 RNA polymerase allows expression of protein from DNA containing the T7 promoter. Col. 2, lines 65 to col. 3, line 3. If eukaryotic cells could express protein from the T7 promoter then Moss would not have needed to create a cell line containing the foreign T7 RNA promoter specifically to achieve that goal.

The claimed subject matter is directed to methods of *in vivo* expression in a mammal using a promoter functional in eukaryotic cells. Li does not teach a promoter functional in eukaryotic cells that would be expressed in mammals. This special technical feature of the invention is *clearly* not in the cited art.

Applicant requests that the Restriction Requirement be withdrawn. At most, claims 1 and 8 should be considered as linking claims and the election of bacterial, yeast, or insect cells should be species elections.

Respectfully submitted,

BANNER & WITCOFF, LTD.

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Dated: April 23, 2009

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